

CLAIMS

1. A drug delivery composition comprising 2-[2-(nitrooxy)ethoxy]ethyl {2-[(2,6-dichlorophenyl)amino]phenyl}acetate in melted form absorbed/adsorbed onto/into particles.
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2. The drug delivery composition according to claim 1 whereby the materials of the particles selected from the group consisting of mannitol and lactose, optionally in admixture with one or more substances selected from the group consisting of
10 microcrystalline cellulose, cellulose and starch.
3. The drug delivery composition according to any one of claims 1 to 2 wherein the particles have a size between 50 and 500 µm.
- 15 4. The drug delivery composition according to claim 3 wherein the particles have a size between 100 and 150 µm.
5. The drug delivery composition according to any one of claims 1 to 4 wherein the particles have a pore size between 10 and 1000 Å.
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6. The drug delivery composition according to claim 5 wherein the particles have a pore size between 20 and 750 Å.
- 25 7. The drug delivery composition according to any one of claims 1 to 6 comprising particles comprising 2-[2-(nitrooxy)ethoxy]ethyl {2-[(2,6-dichlorophenyl)amino]phenyl}acetate in admixture with one or more surfactant(s).
8. The drug delivery composition according to any one of claims 1 to 6 comprising a combination of
30 a) particles comprising 2-[2-(nitrooxy)ethoxy]ethyl {2-[(2,6-dichlorophenyl)amino]phenyl}acetate and one or more surfactant(s),
and

b) particles comprising 2-[2-(nitrooxy)ethoxy]ethyl {2-[(2,6-dichlorophenyl)amino]phenyl} acetate without surfactant.

9. The drug delivery composition according to claims 7 and 8 wherein the surfactant(s) is a
5 non-ionic surfactant.

10. The drug delivery composition according to claim 9 wherein the surfactant(s) is a block
co-polymer.

10 11. The drug delivery composition according to claim 9 wherein the surfactant(s) is a
poloxamer.

12. The drug delivery composition according to claims 7 and 8 wherein the ratio
drug:surfactant(s) is from 1:0.1 to 1:10 (w/w).

15 13. The drug delivery composition according to any one of claims 1 to 12 wherein the
particles comprising the drug, optionally in admixture with one or more surfactant(s), are
mixed with pharmaceutically acceptable diluent, excipients and/or inert carrier.

20 14. The drug delivery composition according to any one of claims 1 to 13 wherein the
particles comprising the drug are formulated into a tablet.

15. The drug delivery composition according to any one of claims 1 to 13 wherein the
particles comprising the drug are filled into a capsule.

25 16. The drug delivery composition according to any one of claims 1 to 13 wherein the
particles comprising the drug are suspended in a water solution.

17. The drug delivery composition according to claims 14 and 15, which is coated.

30 18. The drug delivery composition according to any one of the claims 1 to 17, for use in
the treatment of pain and/or inflammation.

19. Use of the drug delivery composition according to any one of the claims 1 to 17 for the manufacture of a medicament for the treatment of pain and/or inflammation.
- 5 20. A method of treatment of pain and/or inflammation, comprising administration to a patient in need of such treatment, the drug delivery composition according to any one of the claims 1 to 17.
- 10 21. A process for preparing particles comprising 2-[2-(nitrooxy)ethoxy]ethyl {2-[(2,6-dichlorophenyl)amino]phenyl} acetate comprising mixing the drug in melted form with particles.
- 15 22. A process for preparing particles comprising 2-[2-(nitrooxy)ethoxy]ethyl {2-[(2,6-dichlorophenyl)amino]phenyl} acetate comprising:
- 15 a) melting the drug,
 - b) adding the particles,
 - c) stirring the obtained mixture,
 - d) recovering the porous particles comprising the drug.
- 20 23. A process for preparing particles comprising 2-[2-(nitrooxy)ethoxy]ethyl {2-[(2,6-dichlorophenyl)amino]phenyl} acetate comprising:
- 20 a) mixing the drug with the particle,
 - b) melting the obtained mixture,
 - c) stirring the obtained mixture,
 - 25 d) recovering the particles comprising the drug.
- 25 24. A process for preparing particles comprising 2-[2-(nitrooxy)ethoxy]ethyl {2-[(2,6-dichlorophenyl)amino]phenyl} acetate and one or more surfactant(s) comprising:
- 30 a) melting the drug and the surfactant(s),
 - b) adding the particles,
 - c) stirring the obtained mixture,
 - d) recovering the particles comprising the drug and the surfactant(s),

with a) and b) in optional order.

25. The processes according to any one of claims 22 to 24 whereby the drug in step a) is pre-heated.

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26. A process for the preparation of the drug delivery composition according to claims 14 or 15 comprising;

a) mixing the particles, obtained according to any one of the processes of claims 21 to 25, with pharmaceutically acceptable diluent, excipients and/or inert carrier,

10 b) granulating the obtained mixture with water,

c) drying the granulate,

d) optionally mixing the granulate with further diluent, excipients and/or inert carrier, and

e1) filling the granulate into capsules,

15 or

e2) compressing the granulate into tablets.